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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,418	07/07/2000	Raymond P. Johnston	54971USA3A.006	8574

7590 07/16/2002
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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/16/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/612,418

Applicant(s)
Johnston et al.

Examiner
Ardin Marschel

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/15/01, 2/19/02, and 4/26/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above, claim(s) 10-12, 14-38, 42, 47, 48, 51, 52, 55-59, 62-71, 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77, and 81-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-101 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on Apr 26, 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) pages (10 sheets) 6) ☐ Other:

Applicants' election without traverse of Group I, specie F, (claims identified by applicants to read on the elected species: 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77, and 81-85) in Paper No. 9, filed 10/15/01, is acknowledged.

The Abstract of the Disclosure is objected to because it is longer than 150 words. A new abstract submitted on its own separate sheet of paper is required. See M.P.E.P. § 608.01(b).

Claims 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77, and 81-85 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The above listed claims are confusingly not commensurate in scope with the description of the invention in the specification. Particularly, the above claims require that there be "uninterrupted fluid flow of a fluid sample throughout the article" (claim 1, line 4, for example). None of the depicted or described articles in the Figures or specification include this characteristic. For example, "throughout the article" is a phrase that is reasonably interpreted as describing a complete access of fluid to all of the article components or parts. In the specification on page 12, lines 1-8, the articles of the invention are apparently cast or embossed out of various materials, mostly plastics, which normally are solid items after

said casting or embossing. Solid items prevent fluid flow through them. For example, a cast plastic sheet is normally understood to be non-porous unless drilled or cast with holes therethrough. Even a plastic sheet with holes does not permit fluid to soak or wick through the plastic per se. Similarly, Figures 1a-1j and other Figures show channels on their surface but no access throughout these items. Figure 1a, for example, would apparently permit fluid in the jagged channels but not through the cross-hatched solid portion of the device. Clarification is requested via clearer claim wording as to the apparent conflict between the specification, figures, and claims as to flow "throughout the article".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-7, 13, 39-41, 43-46, 53, 54, 60, 61, 72-75, 77, and

81-85 are rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by any one of the following: Beaver et al. (P/N 4,469,601); Hagen et al. (P/N 4,810,381); or Fitzpatrick et al. (P/N 5,451,504).

Each of the above listed three U.S. Patents disclose thin layer detection articles or apparatus. Each discloses the presence of a fluid control layer as a fibrous material through which sample solution freely and uninterruptible flows during the performance of the assays practiced with these devices. The samples are spotted onto the various devices and spontaneously wick into the fluid control layer for transport into the device. The fibrous nature of these devices includes a plurality of microchannels therein for fluid flow throughout the devices. These characteristics anticipate the above listed instant claims. Specifically a device as summarized above is depicted in Beaver et al. at Figures 9-14 and described more in detail in the specification in columns 6-10 therein in a two-dimensional format. The elected specie of an assay reagent in the device is disclosed via the solvent in the strip in column 6, lines 6-29. It is noted that there is no instant limitation as to what is meant by the elected specie as a reagent and thus is reasonably deemed to include any chemical material which mediates or is utilized in the device assay practice and thus also supports reagents as in instant claims 54 and 61 which must operate in

solvent. Similarly, Hagen et al. depicts such a fibrous detection article in Figures 1-3 wherein also the detection versus spotting or acquisition zones are clearly shown. Hagen et al. in the specification in columns 4-10 also give details such as coatings. Such coatings as described in column 4, lines 53-65, improve selectivity or transport via polarity alteration which modifies surface energy as required in instant claim 13. Solvent or assay reagent flow is disclosed in column 8, lines 32-66. Lastly, and again similarly, Fitzpatrick et al. depicts an detection article in its sole drawing clearly showing application or acquisition, mobilization, detection, and absorbent zones which also documents the fluid transport uninterrupted throughout the device. Columns 2-11 give more details including solvent assay reagent in column 3, lines 19-26, as required for the elected instant specie. Thus, these disclosures anticipate the above listed instant claims.

In the IDS, filed 11/24/00, several copending applications were cited. These have been considered but cannot be listed on a form 1449 or 892 due to a lack of a date of publication. These are the following: 09/099,269; 09/099,555; 09/099,562; 09/099,632; 09/100,163; 09/106,506; 09/235,720; and 09/099,565.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

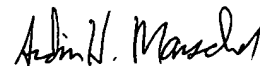
in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 12, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER